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Original communication

Analysis of obstetrics and gynecology professional liability claims in Catalonia, Spain (1986–2010)[☆]



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ABSTRACT

Objective: To identify relevant factors involved in obstetrics and gynecology (OG) professional liability claims to help archive better management of risks.

Study design: Analysis of 885 OG claims opened between 1986 and 2010, with the identification of the most common events leading to a claim, the economical and juridical characteristics of the claims, as well as the relevant trends over the study period.

Results: Most claims related to obstetrics. Labor, delivery and its complications accounted for 33.1% of the claims; 12.77% related specifically to cesarean. Oncological diseases, fetus death during labor and delivery, neurologically impaired infant and hysterectomy-related problems were the most frequently claimed events. Most cases ended up without an indemnity payment and 37.7% of closed files were solved by an out-of-court procedure. Average payment was higher for the obstetric procedures than for those concerning gynecology cases. The proportion of claims relating to obstetrics increased during the study period, as well as the average payment.

Conclusion: OG is at high-risk for malpractice claims, but compensation awards are not frequent. However, particular events, such as retained foreign objects, tubal ligation, ultrasound diagnosis or neurologically impaired newborns, deserve special attention regarding medico-legal issues.

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1. Introduction

Increasing malpractice litigation risks and medical liability insurance premiums have caused widespread concerns regarding their effects on medical care.¹ Archiving safe patient care has become an increasing focus of the medical community.

Obstetrics and Gynecology (OG) is among the specialties at high-risk for malpractice claims and the obstetrics' field accounts for most of the claims.² The influence of medical liability issues on OG practice remains unclear, but it has been reported that litigation risk changes specialists' practice and is one of the most cited factors

by physicians to influence their decision on whether to provide obstetrical care.^{3,4} Most allegations in obstetric lawsuits against obstetrician–gynecologists relate in some manner to the management of labor and delivery⁵; other reported bases of allegation relate to multiple pregnancies,⁶ prematurity,^{7,8} obstetric ultrasound² or fetal monitoring.⁹ Shwayder¹⁰ described nine prime areas for obstetrical litigation: errors or omission in antenatal screening and diagnosis, in ultrasound diagnosis, the neurologically impaired infant, neonatal encephalopathy, stillborn or neonatal death, shoulder dystocia, vaginal birth after cesarean section, operative vaginal delivery and training programs. All subspecialties in the field of OG have major professional liability risks and it has been suggested that the trend toward obstetrics could be counterbalanced by greater payments per lost claim in other areas, such as gynecologic oncology or maternal–fetal medicine.¹¹

Reducing liability risk requires an understanding of the prime reasons physicians are sued.¹² Litigation climate may differ from

[☆] The study was conducted in Spain.

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one country to another¹³ and different scenarios need to be studied to achieve a comprehensive international picture. Malpractice law in Spain resembles international laws, but the malpractice crisis is not as intense.

We present an 885-malpractice-claims analysis in OG, exploring the clinical and legal characteristics of the sample. To our knowledge, such a large and comprehensive analysis of malpractice claims in OG has not been published previously. Findings from this study will help identify the specific areas at high risk for malpractice claims and maintain patient safety associated with OG care.

2. Materials and methods

The Professional Liability Department (PLD) of Barcelona's Official College of Physicians has its own Claims Database. It collects information from the main liability insurance company in Catalonia (24,063 physicians in 2010). The data sources consist of clinical records, narrative statements, expert and peer reviews, deposition summaries, outcome reports and the cost of the settlement or award. Expert physicians and lawyers use a standardized electronic-form to collect information on patient data, clinical characteristics, adverse events and procedure outcomes.

Claim-files concerning OG were identified and reviewed. For the purpose of the analysis, the events that caused the claim were classified in different categories according to the clinical data collected in the review. The solving procedure was dichotomized as “court” versus “out-of-court”, depending on the courts participation in the resolution. The PLD process of negotiating/litigating medical liability cases begins with the issuance of an opinion by the Legal Medicine Unit and PLD's lawyers. The case passes through different expert committees that make a decision: considered “non-risk”, worthy of financial agreement or arguable in courts. Claimants or their attorneys receive the resolution and decide if they want to withdraw the claim, negotiate a financial agreement or go to the courts. Outcomes were dichotomized as “with” versus “without consequences”, according to whether or not indemnity payment was made. Cases' awards were registered (allocated loss expenses and attorney fees not included).

We performed a descriptive analysis of the most common events leading to a claim during our study period, their economical and juridical characteristics and procedure trends of OG claims over time. Differences between groups were compared with the chi-square analysis and Kruskal–Wallis test with $P < 0.05$ for statistical significance. The statistical software package SPSS 12.0 was used for all data analyses. Ethics Committee approval was obtained.

3. Results

885 OG claims were identified among the 7237 malpractice claims opened between 1986 and 2010. This high percentage (12.23%) ranks OG in second position among the high-risk specialties, after Orthopedics and Trauma Surgery.

Most claims related to obstetrics (548 claims; 61.9%). Labor, delivery and its complications accounted for 33.1% of the claims (a 53.5% of Obstetrics related claims). Claims related to cesarean accounted for 12.77% of the total amount of claims, but most serious events belonged to the other methods of delivery (Table 1). Oncological diseases, fetus death during labor and delivery, neurologically impaired infant and hysterectomy-related-problems were the most important claimed events (Table 2). Among Oncological Diseases, most claims related to breast cancer (73.28%). The most frequently claimed complication of hysterectomy was incontinence (7.55%), but in a high percentage of cases (33.7%) the hysterectomy itself was the claimed damaging event (e.g. emergency hysterectomy after childbirth).

Table 1
Claims related to cesarean delivery..

Claimed event	N (total: 113)	“With consequences”/ closed files
Deaths		
Fetus	33 (73 in the total sample)	6/31
Mother	4 (13 in the total sample)	1/3
Fetus & mother	1 (4 in the total sample)	0/1
Foreign objects	24 (51 in the total sample)	19/21
Neurologically impaired fetus	16 (68 in the total sample)	3/13
Hysterectomy after cesarean	13	2/11
Tubal ligation after cesarean	3	1/2
Cesarean itself	3	0/3
Scalpel burns	3	0/2
Wound infection	2	0/1
Kidney problems	2	0/2
Fetus injury during cesarean	2	1/2
Mother's neurologically impaired	1	0/1
Eventration	1	0/1
VHC infection	1	1/1
Suture problem	1	0/1
Uterine rupture	1	0/1
Intestinal fistula	1	0/0
Oophorectomy	1	0/0

Among closed files (786 procedures), most cases ended up “without consequences” (587 procedures; 74.7%). Claims related to obstetric procedures showed a slightly higher rate of cases solved “without consequences” (74.9%), than those related to gynecological procedures (74.4%), without statistical significance ($p = 0.866$). Among closed files, damaging events related to Foreign Objects showed a significantly higher rate of payment (71.73%) ($p < 0.0005$) than the rest of categories (Table 2).

Among those procedures that ended up “with consequences”, average payment was significantly higher for obstetric (mean

Table 2
Primary claimed events ($n > 15$)..

Procedures	Total of claims	Payment rate (among closed files)	Payment mean (€)
Oncologic diseases	97	13.19% (12/91)	91,460.2
Breast cancer	74	14.28% (10/70)	88,852.2
Uterine cancer	20	11.11% (2/18)	104,500.2
Hysterectomy	80	22.39% (15/67)	57,861.9
Histerectomy itself	27	22.72% (5/22)	
Complications	53	20% (9/45)	
Fetus death during labour and delivery	73	22.22% (14/63)	111,583.5
Neurologically impairment child	68	31.66% (19/60)	477,871.6
Foreign object	51	71.73% (33/)	15,422.1
Gauze	43	70% (28/40)	16,968.2
Others	8	83.33% (5/6)	6763.9
Tubal ligation	49	39.58% (19/48)	35,288.3
Ineffective	28	32.14%	
Complications	13	69.23%	
Ultrasound diagnosis	47	18.42% (7/38)	403,224.2
Brachial palsy	27	26.09% (6/23)	143,025.9
Ectopic pregnancy	25	9.09% (2/22)	115,654.5
Ovary surgery	25	28% (7/25)	55,961.6
Voluntary interruption of pregnancy	23	30% (6/20)	87,579.2
Fertility treatments	20	15.79% (3/19)	69,365.3
IUD problems	16	21.43% (3/14)	12,329.3

€183,100.9; median €96,426.56) than for gynecological procedures (mean €45,650.2; median €28,776.5) ($p < 0.0005$). The “ultrasound diagnosis” and the “neurologically impaired infant” categories accounted for the higher average payment (Table 2). The “neurologically impaired infant” category accounted for 35.7% of the total malpractice coverage costs during the study period (€9,079,561 out of €25,441,024.6).

Among closed files, 296 were solved by an “out-of-court” procedure (37.7%). 62.5% of out-of-court procedures ended up without economical consequences, whilst among court-solved procedures the proportion was 82%, showing a statistically significant difference ($p < 0.0005$). The mean amount awarded in “out-of-court” and court-solved procedures was €122,991.1 (€13,652,012.1 total amount) and €133,966 (€11,789,012.4 total amount) respectively.

Table 3 shows most frequently claimed events during study periods. The proportion of claims related to obstetrics increased from 57.4% ($n = 39$) and 60.8% ($n = 225$) in the 1980's and 1990's, to 63.5% ($n = 284$) in the 2000's ($p = 0.525$). Among Obstetrics related claims the proportion of those exclusively relating to mother's health decreased from the 1980's (20.51%, 8 cases) to the 2000's (12.33%, 35 cases), whilst those exclusively relating to the fetus's health increased (30.77%–56.34%) ($p = 0.063$). Although the proportion of claims relating to Gynecology decreased among the study period, claims relating specifically to oncologic diseases increased (from 7.4% in the 80's to 12.3% in the 2000's). Comparing the 90's and the 2000's those claimed events that decreased significantly were those related with tubal ligations ($p = 0.02$) and mother death during labor and delivery ($p = 0.014$); whilst those related with postpartum mother's complication increased significantly ($p = 0.018$).

The proportion of procedures solved “without consequences” slightly decreased from the 1980's and 1990's (83.8% –54 cases- and 79.2% –261 cases- respectively) to the 2000's (75.2%, 272 cases) ($p = 0.043$). Among those procedures that ended up “with consequences”, the average payment was €60,051.6, in the 1980's, increasing to €138,969 and €126,845.1 in the 1990's and 2000's respectively ($p = 0.133$). The proportion of out-of-court solved claims increased from 33.85% (22 cases) and 35.2% (119 cases) in the 1980's and 1990's, to 40.47% (155 cases) in the 2000's ($p = 0.278$).

4. Discussion

Internationally, obstetricians and gynecologists are sued more frequently than physicians in most other specialties and awards against them can be very large.^{2,14} According to our results, OG should be considered at high-risk for claims, especially obstetric care during labor and delivery (293 claims vs. 1,656,920 childbirths during the study period). The American College of Obstetricians and Gynecologists states that at least 60% of obstetric medical negligence claims relate to events alleged to have occurred during labor and delivery (53.5% in our sample). Baldwin¹⁵ suggested that insurers might consider basing obstetric malpractice premiums on numbers of deliveries. Although most women who give birth do so

without a significant safety incident, a notable minority does experience an adverse obstetric event.¹⁶ Deeply disappointed parents, who expected a healthy baby, may sue the physicians, believing that good perinatal outcome is exclusively dependent on a high standard of care.^{17,18}

It has been repetitively reported that obstetricians' behavior changes because of medical legal concerns, even discontinuing obstetric practice.^{1–4,19–21} Many hospitals are no longer offering trial of vaginal birth after cesarean (VBAC), and the cesarean delivery rate continues to rise over recent years.^{22,23} Higher average malpractice premiums have been associated with higher incidences of cesarean deliveries, lower incidences of VBAC and lower rates of instrumental deliveries.^{14,19,24} Although other reasons for declining VBAC have been reported (such as maternal-safety concerns associated with uterine rupture), liability concerns remains a remarkable decisive factor.^{24,25} Failure to perform, or to perform promptly, a cesarean section despite fetal distress has been reported as a medical negligence.³ A low perceived risk-benefit ratio in cesarean has become widespread, making cesarean a reasonably elective option for childbirth.²⁶ In this new scenario, current training programs may not effectively prepare future specialists for the range of situations they are likely to encounter, neglecting the training on other methods of delivery and keeping the rate of cesarean high. Nevertheless, cesarean deliveries are not exempt from difficulties and they have been associated with a high complication rate,²⁷ especially low-risk cesarean deliveries when compared with planned vaginal deliveries at term.²⁶ Suboptimal cesarean outcomes also led to claims in our sample and 35% required compensation payments, therefore physicians should be aware of this potential liability risk when contemplating an elective cesarean delivery.

Events related with Oncologic Diseases were the most frequent claimed event in our sample, specially those related to breast cancer, and the percentage of claims related to oncologic diseases keeps on increasing since the 80's. The Physician Insurers Association of American's (PIAA) reported in 2002 that the most common and expensive diagnosis resulting in claims is breast cancer, although the most commonly named defendant in such lawsuits was the interpreting radiologist, not the gynecologist.²⁸ In our sample the rate of compensation payment in these procedures was low (13.19%), which may suggest that other reasons than real medical negligence must be underneath those claims. Medical improvements have effectively reduced the incidence and mortality of different oncologic procedures, which could have given the perception that treatment or screening procedures, such as the cytological screening for precancerous and cancerous lesions, are highly accurate.²⁹ In this area, as in many others, the liability issue should be addressed through active patient-physician communication and public education.

Another frequently claimed event was hysterectomy-related problems. 22.72% were based on the discomfort with the procedure itself. Women's right to choose is a significant issue that physicians should keep in mind,³⁰ discussing the procedure in advance and obtaining informed consent if an urgent situation can be expected. Inadequate documentation is common and it compromises legal defense.³² Complications, such as urinary tract injuries are uncommon but associated with a high risk of litigation.³¹

Initiating a file does not prejudice that an adverse event or poor outcome occurred or that the incident was avoidable.³² In our study sample, most claims were solved “without consequences”. Claims may reflect claimants' disappointment and a public belief that bad outcomes should not be tolerated and merit financial compensation and punishment. However, particular events as retained foreign objects showed a significantly higher rate of payment (71.73%). Retained sponges following obstetric procedures are an uncommon

Table 3
Claimed events during the 90's and 2000's (proportion >5% in at least one period).

Claimed events	1990–1999	2000–2010
Oncological diseases	10% (37)	12.3% (55)
Fetus death during labor and delivery	7% (26)	9.6% (43)
Hysterectomy related problems	8.4% (31)	8.7% (39)
Neurologically impaired fetus	7.8% (29)	8.1% (36)
Ultrasound diagnosis	4.9% (18)	5.8% (26)
Foreign object	5.4% (19)	6.5% (29)
Tubal ligation	7% (26)	3.6% (16)
Fetus death during pregnancy	5.1% (19)	3.1% (14)

occurrence and significant morbidity from such an event is unlikely; nevertheless the appropriate implementation of safety measures, for example sponge count protocols, could help reduce the occurrence of suboptimal and compensable outcomes.³³

Our sample showed lower amounts of compensation payments than those reported internationally, both for obstetrics and gynecology.^{28,34} The distribution among subspecialties also differs from that described elsewhere. Barbieri¹¹ reported that the percentage of other subspecialists who made a payment was significantly less than obstetrician–gynecologists but their average payment per claim for subspecialists like maternal–fetal medicine and gynecologic oncology was higher. The average payment per claim in our sample was higher in obstetrics; during the 80's, it was similar to that reported by Rosenblatt in 1989 (60,051.6€ vs. 44,000\$).¹⁹ Although the malpractice crisis is not so intense in our country, trends among the study period showed an increase in the amount paid in those procedures that ended up “with consequences”.

Catastrophic obstetric outcomes, such as neurologically impaired newborns showed a high rate of compensation payment (31.66%), slightly lower than the 47% reported in the PIAA's 1998 study.³⁴ It has been reported that the key predictor of compensation in malpractice cases is not the presence of provider negligence, but the degree of patient disability.³⁵ This finding, together with the conclusion established by multiple authors that cerebral palsy is a rarely preventable event given our current state of technology,^{36,37} supports the relevance of patient's degree of disability as a predictor of compensation. In our scenario, a noteworthy legal element is the rule of *Res ipsa loquitur*, which may be invoked in civil courts to shift the onus to the defendant when the facts furnish circumstantial evidence of negligence and direct evidence may be lacking.³⁸ This rule may be invoked when no explanation can be found for cerebral palsy, increasing the chance of a civil sentence.

The largest settlements frequently involved a significantly impaired child, as it had been previously reported.¹⁹ “Neurologically impaired children” cases accounted for a great part of the total costs associated with OG claims (35.7%). The average payment (€477,871.6) is close to that reported in the PIAA's 1998 study (\$478,000 to \$500,000).³⁴ Average payment in the “ultrasound diagnosis” category was also very high in our sample (€403,224), as these cases frequently involve significant disabilities. Because damages are based on the life expectancy of the infant and advances in medical care have led to increased life expectancy for impaired persons, suits can be expected to have large economic damages and the legal path becomes an option for financial support for the expenses associated with optimal long-term care of children.^{2,18} Claims related with breast cancer showed the second highest aggregate indemnity awards with an average payment of \$438,047 in the PIAA's 2002 report²⁸ vs. €88,852 in our sample, showing a remarkable difference in the value given to delayed diagnosis between both countries.

Finally, the increase in the proportion of out-of-court procedures among the study period deserves a special mention. Being a defendant in a medical professional liability lawsuit can be one of life's most stressful experiences and several alternative dispute resolution methods are suited to resolving medical malpractice disputes.^{39,40} Therefore the PLD encourages pretrial settlement of meritorious claims, protecting the physicians from this unpleasant situation and archiving fine results in regard to payment rates and costs.

OG is at high-risk for malpractice claims, but compensation awards among OG claims are not frequent. Simply stated, claims are likely to be triggered by bad outcomes but very few malpractice claims actually involve medical negligence. However, particular events, such as retained foreign objects, tubal ligation, ultrasound diagnosis or neurologically impaired newborns, deserve special attention regarding their payment rate and average payments. In

order to protect patients against faulty practices and protect physicians who act reasonably, safety issues in these areas should be strongly addressed.

Ethical approval

None declared.

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Conflict of interest

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We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

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